SpaceStation
and SpaceCom

Instructions for Use

CE 0123

GB Valid for Software 695F

B BRAUN

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PATIENT SAFETY

Important Information and Notes for Patient Safety

⚠ Attention: Consult accompanying documents!

- Read Instructions for Use prior to use.
- The user must check functional safety and integrity of the Space System.
- Prior to use check functions of the Space System: Valid only for Space System.*
- Functional tests and Technical Safety Checks have to be carried out separately for all additional connected devices.
- Check and set up connections to mains and further plug connections.
- Check if mains voltage corresponds to indication on the type plate!
- When connected, check staff call (simulate alarm, staff call must react).

Warnings:

- Use of the Space System only by qualified staff.
- Use Space System only when you are instructed to work with and familiar with it.
- This Instructions for Use is part of the Space Systems necessary for proper use.
- The Instructions for Use have to be available at the Space System.

Proper Use:

- The modular Space System is made for treatment of a single patient. It is especially designed for use on Intensive Care Units and Operating Theatres. The Space System is used in hospital. Operation mainly by physicians and medically qualified nursing staff.
- Check if the current software and hardware version of the components of the Space System are the same as this Instructions for Use refers to.
- At fm mobil, accessory for mobile use, it is not permitted to use short stands, as the centre of gravity of the Space System may change.
- Insert receptacle suspension of the fm mobil before transport.
  Check stability and secure position, especially when fastening the system to the fm mobil.
- Prevent the fm mobil from rolling away on horizontal surfaces by using the locking device. If there is an incline of more than 5°, additional locking is necessary.
- When the pumps in the Space System are switched off the control systems are not active. Therefore, close roller clamp or selector valve at the connection point to prevent uncontrolled backflow.
- Do not plug the power supply lead into the socket before the whole system is built up.
- The Space System is designed for operation with a single power supply connection per pillar.
- All configurations must comply with IEC/EN 60601-1-1.
- Possible explosion hazard if used in presence of flammable anesthetics!
- Use only compatible combinations of equipment, accessories, working parts and disposables.
- Use only original spare parts. Functional safety is only guaranteed if by the manufacturer recommended resp. compatible disposables are used.

- Read carefully Instructions for Use of the infusion pumps and infusion syringe pumps used.
- Application of infusion and infusion syringe pumps only under regularly supervision by specially trained staff.
- The user must make sure the pumps and other components of the system are locked correctly.
- Do not deposit things on the pumps. Avoid leaning on the pumps!
- The connecting leads must be laid so that people do not stumble over them and work with the Space System is not hampered.
- Do not place disposable near the connections of the pumps – use hose routings.
- Make sure the pumps are inserted and removed correctly.

Transport:

- With max. 4 pumps. Be especially careful when a patient is connected. Avoid external mechanical action!

Only for use of:

- Infusomat® Space
- Infusomat® Space P
- Perfusor® Space
- SpaceControl
- SpaceCom

- Some components have further Instructions for Use or assembly instructions, which need to be observed.
- Therapeutic or diagnostic conclusions must not be based exclusively on values displayed on infusion pumps or data available via interfaces.
- The Space System should only be operated in areas which are well protected against vibration, dust corrosive and explosive gases, extreme temperatures and humidity. To guarantee sufficient air circulation for cooling the system, there should be at least 5 cm of clear space around the system. Do not cover the ventilation slots. The equipment must be free of condensate during operation.
- When equipment with high electro-magnetic radiation is used at the same time (e.g. digital telephones, X-ray apparatus, MRI, etc.) interference may occur. This may lead to display trouble or implausible values may be indicated. If these problems are due to electro-magnetic interferences, the following measures may help to avoid or solve them:
  - Avoid using devices which are not necessary from the medical point of view (e.g. mobile telephones).
  - Extend distance between source of interference and the medical product.
  - Alter position of power supply leads, connection leads and electrodes.
- The EMC-limits (electro-magnetic compatibility) according to IEC/EN 60601-1-2 and IEC/EN 60601-2-24 are maintained. If the equipment is operated in the vicinity of other equipment which may cause high levels of interference (e.g. HF surgical equipment, nuclear spin tomography units, mobile telephones) maintain the recommended protective distances for these devices.

- The Space System should not be exposed to excessive magnetic fields (e.g. in an MRI room). If necessary, longer infusion lines can be used. When using a defibrillator, precautions must be observed which can be found in the documentation for the defibrillator.
- For the safe use of Space infusion pumps in MRI the SpaceStation MRI is recommended.
- In any case of central alarm (e.g. from staff call) it is necessary to check which infusion pump caused the alarm. Only the specified alarm caused by the infusion pump is relevant for safety.
  Direct contact of the connectors of the SpaceStation during operation can lead to malfunction due to electrostatic discharge.

Parallel infusion:
Compared to single infusions increased bolus volumes and alarm delay times may occur!
Therefore:
If possible, select low pressure settings.
Pay attention to bigger bolus volumes and alarm delay times.
When removing sealing, do not let the bolus reach the patient.
A bolus reduction may lead to an underdosage of the drug when starting the infusion again.
Recommendation: bolus reduction by opening the outward conducting system.
The bolus reduction may lead to dosage variations.
Higher personal supervision with critical drugs.
Immediate reaction in case of alarm!
When switching off a pump temporarily bolus administration is possible due to enrichment of concentration at reduced flow.

International safety standards:
The Space System complies with:
- IEC/EN 60601-1,
- IEC/EN 60601-1-1,
- IEC/EN 60601-1-2 as well as
- IEC/EN 60601-2-24

and is CE marked in compliance with EU-Directive 93/42.

B. Braun Melsungen AG is certified according to DIN EN ISO 9001 and DIN EN ISO 13485.

This certification also includes maintenance and service.

The visible LED's comply to class 1 LED products according to IEC/EN 60825-1.

The B. Braun Space System is a flexible docking and communication system for the medical workplace, in particular the intensive medical care, which substantially contributes to the safety of its patients.
It serves the perspicuous accommodation of the infusion and infusion-syringe pumps Infusomat® Space, Infusomat® Space P and Perfusor® Space, whose concrete application is the medical professional decides on based upon guaranteed

characteristics and technical data. The pillar and mounting system synchronized system components enables the individualized workplace design.
The Space System is flexible due to fast and space saving assembly and disassembly as well as the possibility to use it as a mobile, wall or ceiling unit.

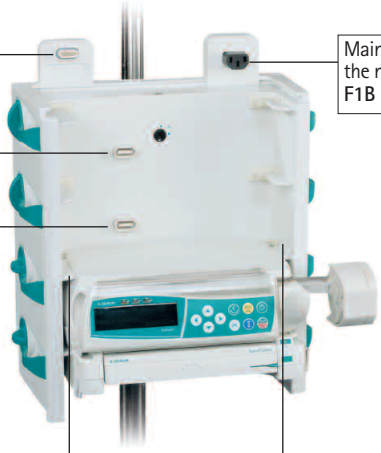
Fur further descriptions as well as assembly resp. disassembly please see this Instructions for Use.

Transport damages:
Inspection on delivery. Despite careful packaging, the risk of transport damage cannot be entirely prevented. Upon delivery, please check that nothing is missing. Do not use a damaged device. Contact the service department.

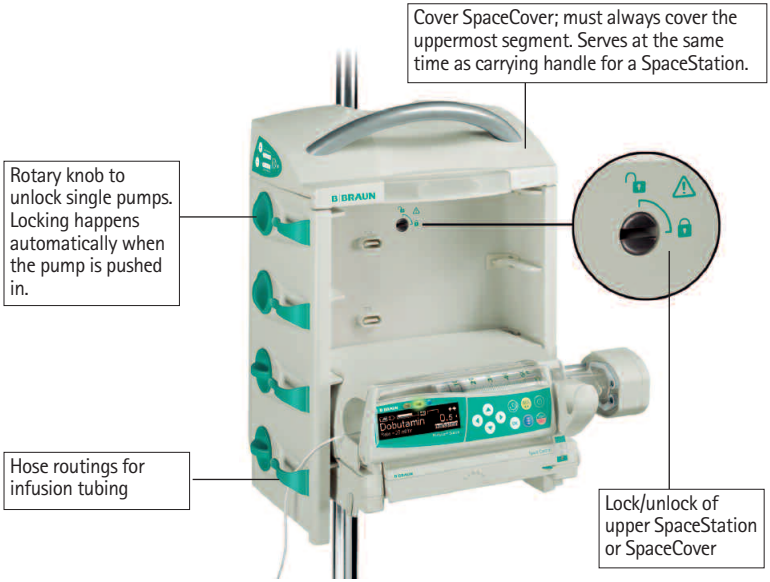
Packaging:
Packages are designed in a way that:
- electrostatic charges are prevented and
- batteries on printed boards cannot be discharged.

THE SPACESTATION IN DETAIL

SpaceStation serves to accommodate up to four infusion and infusion syringe pumps. The single SpaceStations can be assembled to form one or up to three pillars which are separated from each other. The individual pillars require their own mains supply and are interconnected with each other via special extension cables. Every pillar must be closed with a cover, SpaceCover Standard or Comfort, to ensure safe and complete system functionality.


Connector for further SpaceStations or SpaceCover comfort; **F5**
Connector for Space pump. Data lines and 12 V voltage supply; **F2A to F2D**
Mains voltage outlet to the next SpaceStation; **F1B**
Guide rails for the individual pumps

Central loudspeaker, only contained in SpaceCover comfort
Lever to release universal clamp
Fixture of universal clamp SP, rotatable for attachment to wall rails and infusion poles
Mains power input; **F1A**
Connection for extension cable for further SpaceStation; **F4**
Connection for staff call, PCA button, Connection Lead SP 12V and service cable; **F3**
⚠ Attention: Do not connect the Power Supply SP to this connector

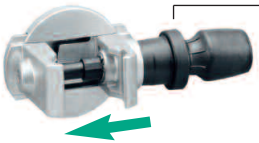

Cover SpaceCover; must always cover the uppermost segment. Serves at the same time as carrying handle for a SpaceStation.
Rotary knob to unlock single pumps. Locking happens automatically when the pump is pushed in.
Hose routings for infusion tubing
Lock/unlock of upper SpaceStation or SpaceCover
B BRAUN
Dobutamin

⚠ Attention: Every SpaceStation or one pillar consisting of several SpaceStations must be covered with SpaceCover standard or comfort. The SpaceCover protects the upper connections from humidity and damage and ensures perfect system functionality. The SpaceStation and the individual pump are connected to each other via the connectors F2A to F2D. The plugs are to be protected from damage and humidity.

1.1 Fastening a Single SpaceStation

Every single SpaceStation can be attached to infusion poles and vertical tubes, e.g. pendants suspension, as well as to horizontal wall rail systems according to EN 1789 without need of any further adapters or assembly auxiliaries. The rear universal clamp can be rotated and has a quick-action mechanism. By pulling the release ring back, the slide can be moved freely and prepositioned. Now the SpaceStation can be definitely fixed by means of the set screw.

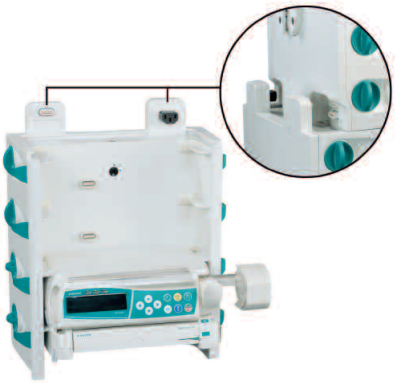
⚠ Attention: Make sure that the SpaceStation is fastened correctly and safely after



By pulling the release ring back, the slide can be moved freely for prepositioning.

assembly. Do not use tools to tighten the screw !

To release, first loosen the clamp by turning the adjusting knob half and then pull the release ring in order to loosen the pole clamp using the quick gripping mechanism.



1.2 Assembly and Disassembly of Pillars

The upper segment is pushed on the lower segment from the front and fixed with the locking in the lower segment.

To release, move the locking button in the corresponding position and take out the upper segment to the front.

⚠ Attention: Every single SpaceStation must be fixed to a fastening tube by means of a fixation clamp.

1.3 Combining Individual SpaceStations

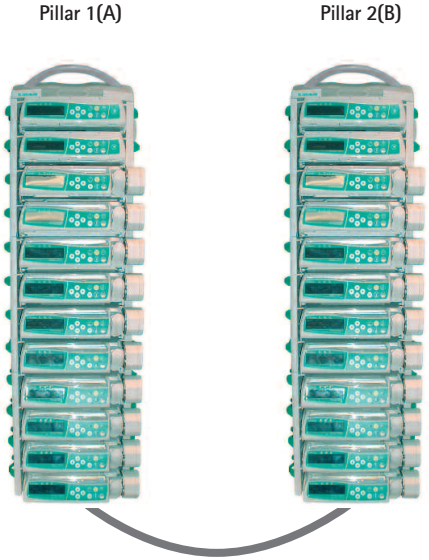
To mount one or multiple pillars the single SpaceStations can be assembled easily and without any difficulties without requiring any special assembly tools.

The admissible combinations are listed in the following table:

	1 Pillar	2 Pillars		3 Pillars		
	A	A	B	A	B	C
SpaceCover Comfort	1	1	(1)	1	(1)	(1)
SpaceCover Standard	(1)	(1)	1	(1)	1	1
SpaceStation	1 ... 6	1 ... 5	1 ... 5	1 ... 4	1 ... 4	1 ... 4
Restriction	$A \leq 6$	$\sum A + B \leq 6$		$\sum A + B + C \leq 6$		

(x) alternative usage possible A,B,C number of SpaceStation in one pillar

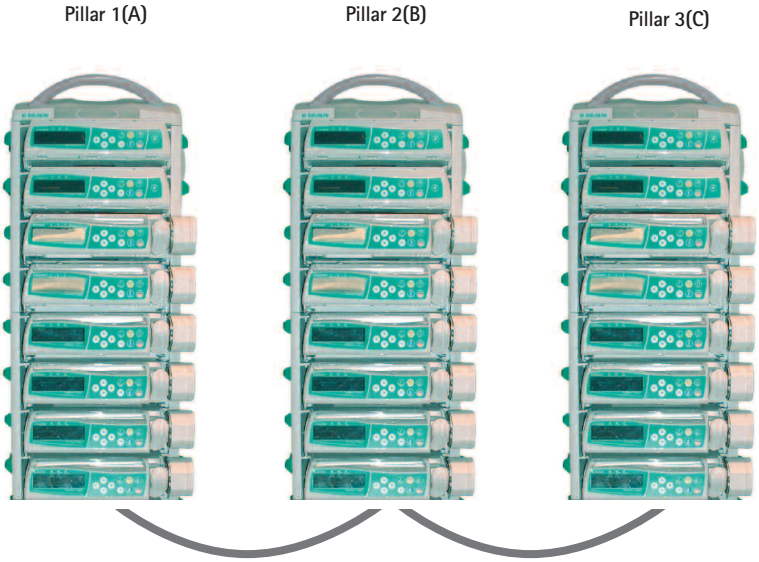
⚠ Attention: Other configurations, such as more than three pillars or exceeding the number of SpaceStations within a pillar, are not permitted and result in configuration error.
If a system consists of several pillars, these should be arranged logically and physically from left to right.



Extension lead SP 60 or 120 cm. The lead is connected to F4 in pillar 1 and then to F3 in pillar 2.

⚠ Attention: If the pillars will not be connected as described above, interchanging F4 and F3, there is a wrong topological representation in SpaceOnline and wrong addressing in the BCC protocol.

Every single pillar must be covered with a SpaceCover standard or SpaceCover comfort. If with a two or three pillars build up and only one SpaceCover comfort is used in this combination all alarms and status information are displayed at this Cover. In case every pillar is covered with a SpaceCover comfort the status and alarm information are shown at the corresponding cover.



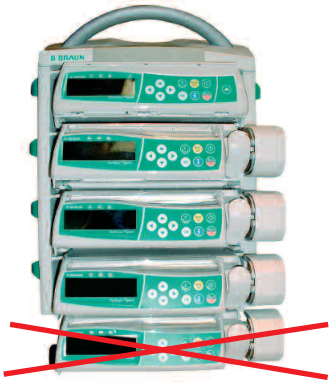
Extension lead SP 60 or 120 cm. The lead is connected to F4 in pillar 1 and then to F3 in pillar 2. Pillar 2 and 3 are interconnected with each other via F3 and F4.

COMBINATION OF PUMPS WITHIN A SPACESTATION

The following pumps and modules can be combined within a SpaceStation.:

- 4 pumps; Infusomat® or Perfusor® Space and optional SpaceCom
- 3 Space pumps and 1 SpaceControl and optional SpaceCom
- 2 Space pumps and 2 SpaceControl and optional SpaceCom
- 4 Space pumps and 1 SpaceControl, attached to the lowest pump in the system and optional SpaceCom.

⚠ Attention: **Danger of tipping !**
An operation as tabletop unit is **not allowed. Operation is only allowed if mounted on a stable infusion pole.**



⚠ Attention: The operation of a fifth pump mounted under the lowest pump in the system is not allowed.

INSERTING AND REMOVING INDIVIDUAL PUMPS

⚠ Attention: Before inserting a pump please ensure the vertical position of the side rotary knob.
The guide rails of the SpaceStation must engage in the guide grooves of the pump. The pump is then pushed with light pressure into the Space Station. The pump is automatically locked in the system. The locking is to be recognized by the horizontal position of the side rotary knob.

To release, turn the knob clockwise in the vertical position and remove the pump. After release the pump is held in the SpaceStation by the guide rails, but can drop easily due to strong vibrations or during transport.

⚠ Attention: If a SpaceStation is used to transport infusion pumps make sure that the pumps are correctly seated in the system.
A combination of Space pump and SpaceControl is installed in the SpaceStation in the same way. In this case pump and SpaceControl are automatically and individually lokked. Before removal, first release the pump and then SpaceControl and then remove both systems. For detailed information please refer the instructions for use of SpaceControl.

⚠ Attention: After connecting a pump the blue LED starts flashing for a short time. In case the blue LED is illuminated constantly, a non critical fault is detected. By disconnecting and connecting the pump again, the fault could disappear, observe blue LED. If the blue LED stays illuminated please inform the technical service. The pump can be used furthermore but the status is not shown at the SpaceCover comfort, green/yellow/red LED at cover, and communication with external systems, PDMS, SpaceOneView, or staff call, is not working anymore. Status information are only shown at the pump directly.

SPACECOVER STANDARD

The SpaceCover Standard does not contain any additional electronics. It protects the upper connectors from humidity and damage and allows a single SpaceStation to be used as a carrying unit.

⚠ Attention: Make sure that the SpaceCover is always correctly fixed. Please refer also to the „Assembly and Disassembly Instructions" of the SpaceStation.

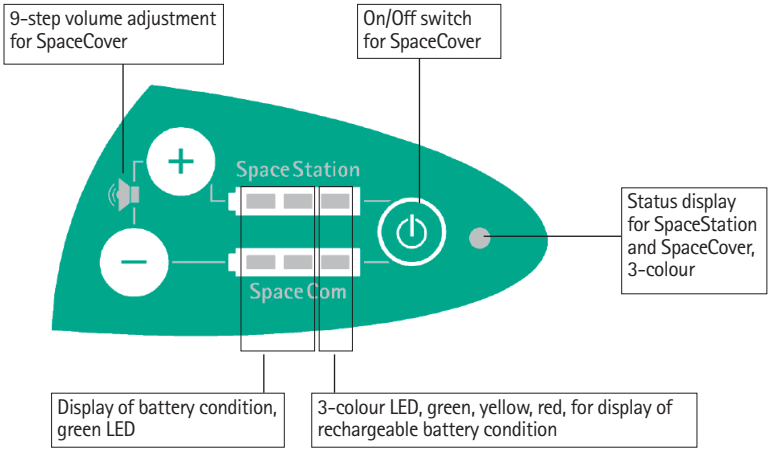
SPACECOVER COMFORT

SpaceCover Comfort offers a greater system functionality and operating facility. Mounted on the front of the cover is a large and clearly visible status and alarm display. All status and alarm conditions of the pumps within the system as well as of the pumps themselves are displayed. The following conditions can be indicated:

- green -> OK; at least one pump in operation
- yellow -> prealarm of one pump in the system
- red -> alarm of a pump in the system

Details concerning the single prealarms and alarms are given in the corresponding instructions for use of the pumps.
In addition, a rechargeable battery (the same as with the pumps) can be inserted in the SpaceCover Comfort. This rechargeable battery ensures complete system functionality in case of transport and even at an interruption of the voltage supply. Furthermore a loudspeaker is integrated in the SpaceCover Comfort to output the alarms of the pumps. The volume can be adjusted in nine steps via the operating elements.

5.1 Operating Elements and Status Display on the SpaceCover


9-step volume adjustment for SpaceCover
On/Off switch for SpaceCover
SpaceStation
SpaceCom
Status display for SpaceStation and SpaceCover, 3-colour
Display of battery condition, green LED
3-colour LED, green, yellow, red, for display of rechargeable battery condition

5.1.1 Display of Battery Condition

The display elements indicate the condition of the rechargeable battery in the SpaceCover and the SpaceCom. The rechargeable battery for SpaceCom is available as an option.

The following conditions are indicated

	LED left	LED middle	LED right
> 75% capacity	●	●	●
> 50% capacity	○	●	●
> 25% capacity	○	○	●
≤ 25% capacity	○	○	●
< 30 min operating time	○	○	flashing
< 3 min operating time	○	○	flashing
Maintenance required	●	●	●
Maintenance active (capacity > 75%)	●	●	flashing
Maintenance active (capacity > 50%)	○	●	flashing
Maintenance active (capacity > 25%)	○	○	flashing
Maintenance active (capacity < 25%)	○	○	flashing

Rechargeable battery SpaceCom (is only displayed when rechargeable battery is installed)

	LED left	LED middle	LED right
> 75% capacity			
> 50% capacity			
> 25% capacity			
≤ 25% capacity			
Battery flat, switched over to SpaceStation battery			flashing
Maintenance required			
Maintenance active (capacity > 75%)			flashing
Maintenance active (capacity > 50%)			flashing
Maintenance active (capacity > 25%)			flashing
Maintenance active (capacity < 25%)			flashing
Error, change battery			

Rechargeable battery SpaceStation

Battery pre- and end alarms can be acknowledged with the buttons of the volume control "+" and "-". Thereby the audible alarm is prevented, the optical alarm is still displayed. Battery alarms are automatically acknowledged when the system is reconnected to the mains.

5.1.2 Switching On /Off

The On-/Off-switch is only operative in battery mode. When the system is connected to the mains voltage, the system is always activated.

⚠ Attention: When the system is not needed and not connected to the mains voltage the SpaceCover should be switched off.

To switch off the system the on/off switch has to be pressed for three seconds. The status LED is flashing for 5 seconds and goes out afterwards.

5.1.3 Volume Control

The volume of the loudspeaker installed in the SpaceCover can be controlled with the buttons "+" and "-". The setting is done in 9 steps, after every new step a high beep signal with the new loudness is given. If the maximum or minimum setting is reached a deep beep is given. The last setting is saved when the system is switched off.

5.1.4 Brightness Sensor

Every SpaceCover Comfort is equipped with a brightness sensor that adapts the brightness of the alarm display in the cover to the environment. The brightness cannot be adjusted manually.

5.1.5 Battery Maintenance Program

To guarantee maximum battery capacity and at the same time a long service life a so-called battery maintenance program is integrated in the system. The battery maintenance is displayed automatically dependent on the operation of the unit. The battery maintenance program can only be initiated when the system is connected to the mains. When the program is running the unit should not be used for transport purposes since otherwise the complete battery running time is not guaranteed. The battery maintenance can be triggered separately for the battery of the SpaceCover and SpaceCom.

When maintenance is necessary the status diode green/green/yellow of the respective battery lights up. The maintenance program is started by pressing the On-/Off-button and the "-" button for the SpaceCom or the "+" button for the SpaceCover simultaneously. During maintenance all green LEDs are flashing and go out when the capacity reduces. When the maintenance program is completed, the batteries are recharged.

⚠ Attention: When battery maintenance is carried out the unit should not be used for transport purposes since otherwise the complete battery running time is not guaranteed.

5.1.6 Status Display

green	->	The system is operated with mains voltage
yellow	->	The system is operated by battery
flashing red*	->	Wrong configuration, check the system setup
red*	->	Unrecoverable error, exchange cover.

*LED in front is flashing also

5.1.7 Self check during start up

During the start up of the SpaceCover comfort a self check is started automatically. The three LED at the front side are tested in the order red, yellow, green and after this the status indicators of SpaceStation and SpaceCom are tested. All green, yellow and red according to "Display of battery condition"

If one of the front side alarm indicator is defect the red alarm LED and the lateral red status LED are illuminated, see 5.1.6.

INTERFACES FOR DATA COMMUNICATION

The SpaceStation does not provide an interface to connect the system into Patient Data Management Systems, PDMS. For the external communication SpaceCom can be used optionally.

SpaceCom can be upgraded or ordered ex works as one unit with SpaceStation. SpaceCom will be installed laterally into a SpaceStation and functions as a central communication interface for all pumps in the system.

For further details about SpaceCom refer to the following paragraphs. Detailed and supplementary information concerning the communication protocol BCC can be requested separately. SpaceCom provides different interfaces, like Ethernet RJ45, RS232, USB Master and Slave, and a PS/2 for data communication and for the connection of accessories. For wireless data transfer a Wireless LAN Adapter can be integrated into SpaceCom. For central access to data of the infusion pumps a web server is integrated, which can be accessed using a standard internet browser.

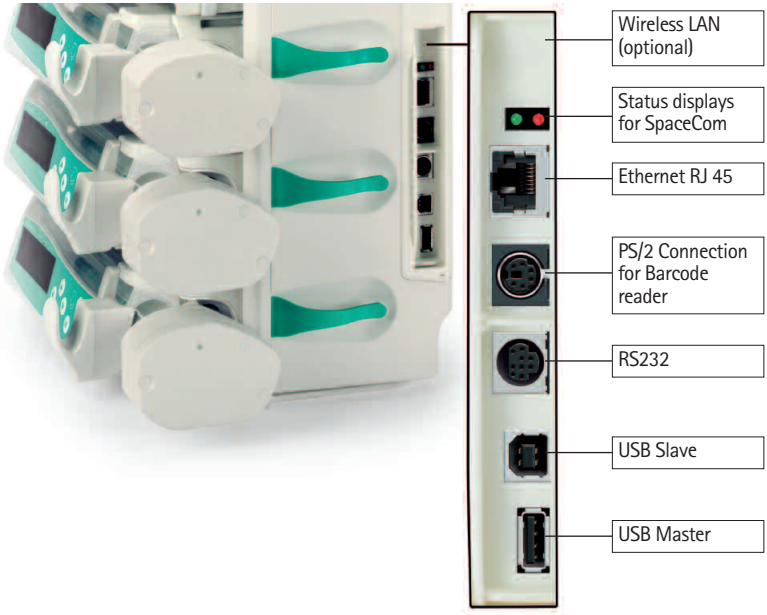
⚠ Attention: SpaceCom with software E is incompatible to Space pumps and SpaceCom with software version C or D. This results in a faulty transfer of parameters in the BCC Protocol and the display in SpaceOnline.
Please ensure that only pumps with software version E are operated together with SpaceCom software version E.

6.1 Intended Use

SpaceCom is used to connect external devices for the data documentation in a Patient Data Management System, PC or USB memory stick.
Therapeutic or diagnostic conclusions must not be based exclusively on values delivered by SpaceCom and their display on a Patient Data Management System or in the web application. In particular the interpretation of alarms does not release the operator from observing the local alarms at the pumps.

It is recommended that you connect only devices which conform to IEC950 or IEC1010, or use accessories specified by B. Braun.

6.2 The connectors of SpaceCom



The RJ45 plug of the Ethernet socket is protected against unintentional removing by a mechanical lock. To remove the plug, slightly press the cap of the plug cover against the plug. This opens the mechanical lock and the plug can be removed.

6.3 Status Displays

In SpaceCom there are two status displays showing the operating status. The green LED signals the operating status. The red LED shows errors. For status indications please refer to the following table:

	green LED	red LED
System starting, not yet ready *		
SpaceCom is ready		
Error during operation		blinking

After starting the system the red LED must go out after approx. 60 sec. Should this not be the case there is an error. Try to remedy the error by re-starting the system. Should the red LED stay on please contact the B. Braun service.

6.4 Inserting and removing battery for SpaceCom

The cover of battery compartment can be opened with i.e. a little coin. Place the battery and fix it with the green hook. The hook must be pressed upwards. To remove the battery pull the hook down.

Battery operation of SpaceCom is only possible if an additional battery is used in SpaceCover comfort.

6.5 Configuration SpaceCom Interfaces

SpaceCom can be configured via a web access. Default IP address for the Ethernet port is **192.168.100.41**. The following parameters and settings can be adjusted:

Parameter	Setting	Settings ex works
IP address Ethernet	Static	192.168.100.41
	DHCP	
	Subnet mask	255.255.255.0
	Gateway	
IP address WLAN	Static	192.168.101.41
	DHCP	
	Subnet mask	255.255.255.0
	Gateway	
Enoding	WEP	not active
	WPA	not active
	TKIP	not active
Communication protocol	BCC	Version 3.25
RS232	Baudrate	9600 8N1

6.6 SpaceOnline, the SpaceCom Web Server Application

Additional access to the infusion pump data is possible via SpaceOnline. A web server integrated in SpaceCom provides different web pages. Access is protected by a password which offers personal or ward- or hospital-wide access control. It is recommended to change the default login after installation. Please refer chapter 7.5.2 for detailed information.

⚠ Attention: The data, the values displayed on the web sites and in particular the infusion pump alarms do not release from observing the local alarm displays at the infusion pumps. Therapeutic and diagnostic decisions must not be made solely on the basis of the displays of the web application.

SpaceOnline offers different Micro-Sites upon which different data or configurations are possible.

6.6.1 Setting of a network connection

To set a network connection on your PC or PDMS (Client-System) please contact the administrator or the manufacturer of the PDMS.
Please set up the network address of SpaceCom via the Web application. Start a browser, MS® Internet Explorer or similar, on your PC and fill in the default address or the newly determined IP address in the address field.

Hint: Always use http:// when accessing SpaceOnline.

As an alternative to the IP address a name in the file "hosts" can be saved in the client system. Please see the documentation of your client system for details.

Important: The browser must accept cookies and allow the execution of Java scripts.

Important: SpaceCom only supports Microsoft® Internet Explorer 6.0 or higher.

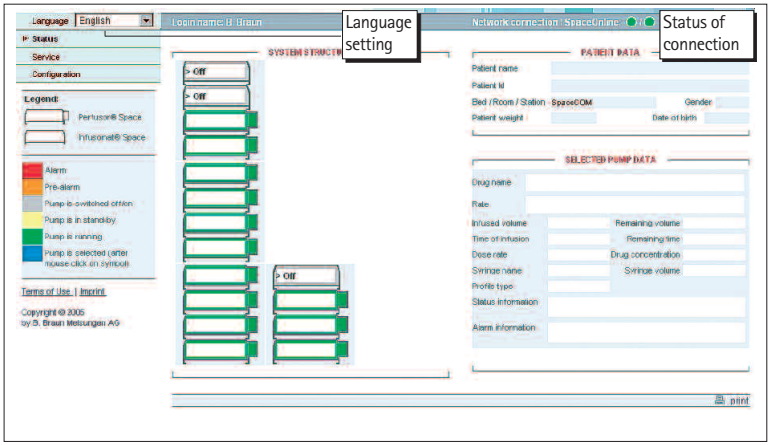
6.6.2 Login

The following user names and passwords are predefined:

user name	password	Activated for
status	status	Status page
service	service	Service page
config	config	Configuration page

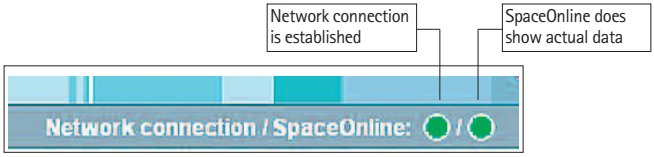
In order to prevent unauthorized access you are recommended to change the individual passwords after first start-up. For further information regarding configuration please refer to the chapter „Configuration – User Settings".

6.7 Status



The status display shows infusion pump data and the system status. The representation of the pumps corresponds with the topological configuration in the system. The present status will be displayed according to the legend. If a pump is selected, detailed information will be displayed on the right. Patient information will only be displayed if it is also saved in the pump. This is available only with pump software version G and higher. The data of the selected pump will be shown according to the pump software version.

A connection status display is integrated in the header.



The network connection between PC or browser and SpaceOnline is shown and the status of SpaceOnline is monitored using the two status displays, red/yellow/green. The displays change their status dynamically. Should one of the two displays stay red for 15 – 20 sec an error is present and the displayed information is no longer up to date. For details please see table below:

Network connection	Status	Cause of Error
green	OK, is are up to date	
yellow	OK, data could not be updated	Application failed
red	Connection failed, data not up to date	Network connection failed, check network and Space-Com
Space Online		
green	OK, data is up to date	
yellow	OK, data could not be updated	Data from SpaceOnline have not yet been updated
red	SpaceOnline failed, data not up to date	Internal error in SpaceCom, try to solve by restarting

6.8 Service

This page contains information about the individual pumps and the system.

6.9 Configuration

Under configuration user settings and configurations can be done.
Important: Changes and new settings only get active after a restart of SpaceCom.
The restart can be done via hardware reset or soft reset with the reboot button

6.9.1 User Settings

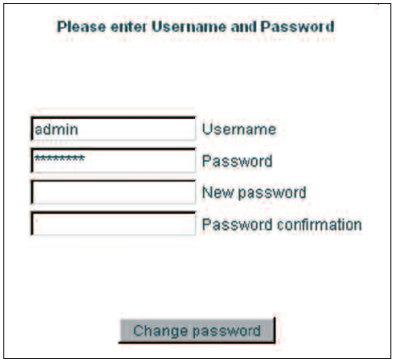
It is possible to administer the password of individual logins, configure the BCC protocol and determine the network settings. The ward ID can also be set.

To restore the factory defaults, listed in this Manual, please select "Set to factory default after reboot", see picture.

An other option is the use of a USB Memory Stick. Create on a stick an empty directory with the name "factorydefault". Connect it to the USB Master port of SpaceCom and do a re-boot be switching the mains power off and on again.

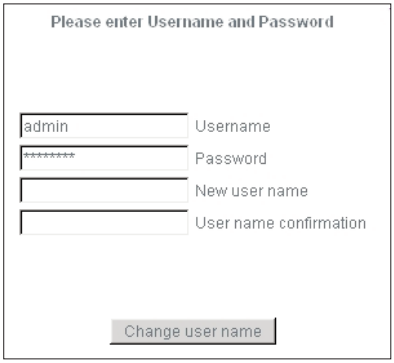
6.9.1.1 Change password

This menu allows to change the password for the user listed under chapter 6.6.2. Press "change password" to activate the new settings.



6.9.1.2 Change user name

The predefined user names can be changed in this menu. However, it is not possible to add new or to delete existing user names.

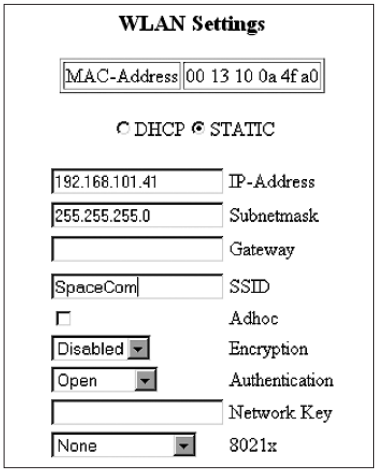


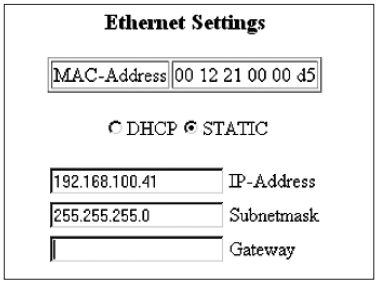
6.9.1.3 Change access authorization

The access authorization can be given for each individual user name. The user access rights can be set and must be confirmed by an appropriate password.

6.9.2 WLAN and Ethernet Settings

For further information how to configure the BCC protocol see the separate interface description.



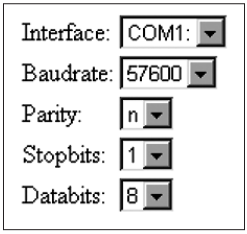


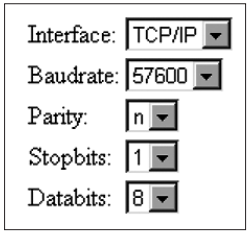
If SpaceCom is operated in DHCP mode you can assign a system name for every individual SpaceCom to address it within your network.

6.9.3 BCC Protocol Settings

SpaceCom provides different communication protocols for data exchange with Patient Data Management Systems. For detailed information about compatible systems, please refer to http://www.space.bbraun.com.

The settings of the baud rate as well as parity, stopbits and databits, comply with the requirements of the PDM system.





You also can setup a TCP/IP interface for the communication with SpaceCom via the BCC protocol. In this case the port 4001 is used in SpaceCom. In this case the other settings for the COM-Port are not used.

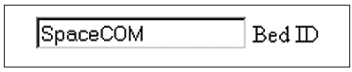
6.9.4 Battery Settings

Here you can determine when the battery maintenance program should be activated. It is given in days and only valid for the SpaceCom battery integrated in the rear panel of the SpaceStation. The settings for the batteries of the pumps and of the SpaceCover comfort are made separately using the service program HiBaSeD.

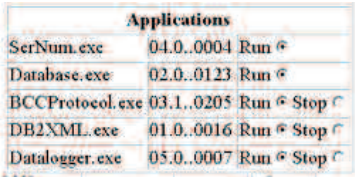
For further information please refer to chapter "Battery Maintenance Program".

6.9.5 Database settings

The ward ID is a feature unique to your system, which appears both in the BCC protocol and on the SpaceOnline display. The ward ID can have up to 15 characters.



Here you can start and stop applications of SpaceCom also. Normally all applications are set active. Changes should be done by service only. the function of SpaceCom is effected by this settings.



BCCProtocol.exe stop or run the external interface for Patinet data Management Systems, BCC protocol.

DB2XML.exe stop or run SpaceOnline.

Datalogger.exe stop or run the internal data logger of SpaceCom, see chapter 8.

6.9.6 Time synchronization via SNTP

To synchronize the time stored in SpaceCom you can link SpaceCom to a time server in your network. Fill in the required information and restart SpaceCom.

6.10 Wireless LAN

⚠ Attention: The optional WLAN card (2,4GHZ, 100mW) can cause interference with devices in the vicinity. Please observe the necessary minimum distance requirements. When using WLAN, the encoding should be activated in order to protect the data connection. The card provides WEP (Wireless Equivalent Privacy) and WPA (WI-FI Protected Access) encoding for this purpose.
For more detailed information about the WLAN operation please see the documentation delivered with the upgrade kit WLAN.

PROPOSAL DATA

7.1 General

The optional function „Proposal Data" is available since software version 68xF030003 or higher versions. On SpaceCom software 695F010003 or a later version is required.

The function "Proposal data" requires a PDMS which is supporting this function. A proposal list is a list of medication with up to 24 medications and the corresponding infusion rate.

7.2 Working with proposal data

The availability of proposal data are displayed at all pumps at the same time. In the upper part of the display at a pump the hint "Proposal" and the first entry of the prescription list is shown.

By pressing the blue Connect-button at the pump the prescription list can be entered.

Navigation within the proposal list:

Via the keys you can scroll through the proposal list. At the end of the list a special menu is shown where additional functions are selectable. These are: Stop signaling proposal data at this pump, delete complete list of proposal data

Selecting an entry:

In case you have selected the right medication from the list, you can confirm the correctness of the data by using the button ▼ . The entries are market with a check automatically. At the end of the list you must confirm the correctness again by pressing the OK button OK .

In case a pump is already infusing the changes are set active after the confirmation with OK, otherwise the pump has to be started manually by pressing Start/Stop The selected medication is deleted from the remaining proposal list and is not shown at other pumps anymore.

By pressing the Clear button C the menu turns to the previous screen. Unconfirmed changes are canceled.

Display of full drug name:

In addition to the display of the short drug name , main display in big characters, you can select within the lower display line the full name of the drug. The content of the lower display line can be controlled by the up and down keys ▼ ▲ Please refer the Instructions for use of the pumps.

Example: Display of long drug name

Attention: The content of the drug name is depending of the linked PDMS.

Changes in proposal list:

In case changes in an already active set of proposal/prescription e. g. infusion rate, are only displayed at the pump which is already operating this drug. All other pumps will ignore the proposal list.

If additional data e.g. new medications are add to the already existing set of proposal data, these data are only displayed at pump which do not have any drug name assigned at this moment.

In case a prescription is stopped at the PDMS the pump will not recognize this change automatically. The drug delivery has to be stopped manually at the pump.

Display of proposal data:

Proposal data are displayed according to the status of a pump. Details are listed below.:

Status of pump	Signaling	Content of proposal list
Pump is switched off and no drug name is shown in the display, usage of last therapy is disabled	Proposal data are displayed	In the upper line of the display Proposal data and the first entry of the prescription list are shown. By switching on the pump the list can be entered.
Pump is switched off and a drug name is shown in the display. Last therapy is enabled.	Only if drug in proposal list is matching the drug name at pump	In the upper line of the display Proposal data and the first entry of the prescription list are shown. By switching on the pump the list can be entered.
Stand by active	Proposal data are displayed	In the upper line of the display Proposal data and the first entry of the prescription list are shown. After ending stand by the list can be edited.
Pump is switch on but not infusing	Proposal data are displayed	List can be entered by pressing the blue connect button .
Infusing and no drug name assigned	Proposal data are displayed	List can be entered by pressing the blue connect button .
Infusing one of the drugs contained in the proposal list	no display	no display of proposal data, only in case of change of infusion rate
Pump is connected to system while proposal data are active	Proposal data are displayed	List can be entered by pressing the blue connect button .
Infusing a drug but infusion rate is changed in proposal list	Proposal data are displayed	Only this drug is displayed in proposal list. Rate is adjusted after confirmation.

Notification signal for proposal data:

It is possible to activate a notification signal which gives an audible signal in case of new proposal data are send to the Space system or a list of proposal data is not completely worn out. This function can be enabled or disabled via the service tool HiBaSeD. The notification is disabled by default.

DATALOGGER

With software 695F010003 there is a data logger available which operated like a trip recorder in your car. The data logger stores the most important data generated by a pump on SpaceCom for up to 8 hours. Only data of pump directly connected to SpaceCom are stored. Historical data from the pump, e. g. from transport, are not downloaded to SpaceCom afterwards. The memory is cleared in case SpaceCom is switched off.

The documentation is related to the drug name delivered from the pump. In case no drug name is assigned the data are stored with type and serial number of the corresponding pump. If a drug name is assigned afterwards, the documentation is continued with the new drug name.

The data can be request with a normal browser by ttp://IP_og_SpaceCom/validate.asp.

By clicking on the drug name, a list with detailed information is displayed on the left side.

Actual medication

Drug name	Slot	Last event
Arterenol 4mg/50	3	Start; Dosisrate 0.01 ug/kg/min
Ciprobay 400 mg/ml	2	Start; Rate 1 ml/h

History of medication

Drug name	Last event
Ciprobay 0.2/100	Drug changed
Disoprivan 20mg	Drug changed
Perfusor 1815	Drug changed
Perfusor 1827	Drug changed

Here are all medication listed which are not active any more. The data are cleared after 8 hours.

SERVICE

The Space System is to be subjected to a Technical Safety Check with registration in the Medical Device Book every 24 months.

The Technical Safety Checks may only be performed by technicians trained by B.Braun or technical personnel of B.Braun Melsungen AG.
Individual agreements take into account the specific conditions of every hospital.

If required a complete Service Manual can be made available, this, however, only combined with a technical training.

Note:
If the Space System is to be integrated in existing wall or ceiling supply systems, please discuss whether this adaptation is permitted with the manufacturer of the supply systems.
The infusion pumps Infusomat® Space and Infusomat® Space P as well as the infusion syringe pump Perfusor® Space are to be submitted to a Technical Check with registration in the Medical Device Book according to the checklist every 2 years.

This 2-year maintenance should be carried out by the service personnel of the manufacturer B. Braun Melsungen AG, or technical staff trained by them.

Responsibility of the Manufacturer

The manufacturer, person who assembles, installs or imports the device can only be held responsible for the safety, reliability and performance if...

- ... mounting, enhancements, new settings, changes or repairs are carried out by duly authorized persons,
- ... the electrical installation in the respective room meets the requirements of the VDE 0100, 0107 or IEC regulations,
- ... the system is used in accordance with the instructions for use,

and

- ... the Technical Checks are carried out at regular intervals.

The CE label confirms that this medical device corresponds to the „Directive of the Council for Medical Products 93/42/EC" of June 14, 1993.

GUARANTEE

B. Braun Melsungen AG puts a guarantee of 24 months on every SpaceSystem counted from the delivery date. For rechargeable batteries a guarantee of 12 months is given.

This guarantee includes repair or replacement of defective parts due to constructional, manufacturing or material defects. The guarantee becomes void if the user or third parties make changes to or repairs on the system. Excluded from the guarantee are:

repairs of defects that can be attributed to incorrect manipulations, improper use or normal wear.

The instructions for use of the Space System can also be reordered after the product service life.

10.1 Maintenance

Operate the system only in accordance with the instructions for use.

Check, clean and disinfect the Space System at regular intervals.

Check for cleanliness, completeness and damages.

Only use original spare parts and accessories.

Carry out the Technical Safety Check or maintenance of the Space System with all additional units connected (e.g. PC) every 24 months (see checklist attached).

10.2 Hygienics / Disposal

Clean the Space System with a mild soap-sud. Do not carry out disinfection by spraying at the mains connections.

Recommendation: Disinfectant for disinfection by wiping from B. Braun (e.g. Meliseptol). Let the unit dry for at least 1 minute before starting operation again. Do not spray in system openings (side openings for necessary cooling, power supply input, interfaces etc).

Heed to the disposal and hygienic instructions!

Dispose of the system according to the country-specific regulations. Old units are taken back and removed by B. Braun on request.

The connectors (see Fig. 3.3 system socket F 1-4) are regularly to be checked for contamination (e.g. spilled fluid) and cleaned, if necessary. For safety reasons the system must be disconnected from the mains while it is cleaned.

10.3 Rechargeable Batteries

Charge the battery before initial start-up.

The mean service life of the batteries is approximately 3 years.

Time of recharging: typically 6 h (NiMH).

In case of a power failure the system automatically switches over to the rechargeable battery (if existing).

Charge and remove batteries out of the unit if the system is not used for a longer period of time (storage time > 2 weeks).

If the batteries are stored for longer time, recharge at least once a year is recommended.

The service life of the batteries can be prolonged if they are regularly completely discharged and recharged at the mains.

Rechargeable batteries must be recycled (special refuse).

TECHNICAL DATA

11.1 B. Braun SpaceStation without B. Braun SpaceCom

Type of unit	System rack for connection of up to 4 infusion pumps	
Classification (acc. to IEC/EN 60601-1)	Defibrillator–proof; CF equipment Protective Class I	
MDD Class	IIb	
Protection type	IP 22 (drip protected)	
Power supply	Primary: 100 ... 240V 50/60Hz 110V 0,46A / 220V 0,23A (mains fuse 2A slow blow) Secondary: 12V DC / 35W (cooling: convection) Duty cycle 100%	
External low voltage supply	11 ... 16V DC ⎓ (via Connection Lead SP 12)	
Staff call	max. 24V / 1A /24VA (via Connection Lead for Staff Call) floating output Observe VDE0834 Pay attention to national requirements	
Earth leakage current (incl. cabling)	one station NC < 0,1 µA SFC < 30 µA	six stations NC < 0,1 µA SFC < 100 µA
Patient leakage current	< 1 µA	
Spark protection	acc. to IEC EN 60601-1-2:2001 and IEC EN 60601-2-24:1998	
EMC	acc. to IEC EN 60601-1-2:2001 and IEC EN 60601-2-24:1998	
Operation in ambulance cars	acc. to 95/54/EG	
Electronic with following functions Use in cars is allowed		
Protection of pump connector	Release of power outlet only if pump is seated in Electronic fuse 12V/1,8A	
Interface to SpaceCom	optional device	
Protection of SpaceCover	Release of power outlet only if cover is mounted Electronic fuse 12V/1,5A	
Configuration of SpaceStation	Dynamic configuration depending of the mounted SpaceStations	

Addressing of pumps	Dynamic addressing related to the position of the pump within the system
Interfaces	
Mains power inlet	Standard cable
Outlet of mains voltage	Connector for power supply of the next SpaceStations
Pump connector	4 connectors (F2A..F2D) for Infusomat® or Perfusor® Space
Connection between modules	Interconnection of several SpaceStation via plugs F3 and F4
Connection to periphery	Connection of accessories PCA button SP Connection lead for Staff Call Connecting Lead SP (12 V) Interface Lead SP via plug F3
Operating conditions	
Relative humidity	30% ... 90%, without condensation
Temperature	5°C ... 40°C
Atmospheric pressure	500mbar ... 1060mbar
Storage conditions	
Relative humidity	20% ... 90%, without condensation
Temperature	-20°C ... 55°C
Atmospheric pressure	500mbar ... 1060mbar
Weight (w/o Cover , with pole clamp)	3.6 kg
Dimensions W x H x D (without Cover)	290 x 327 x 160 mm
Dimensions W x H x D (with Cover)	290 x 364 x 160 mm

11.2 B. Braun SpaceStation with B. Braun SpaceCom

Like B. Braun SpaceStation without B. Braun SpaceCom with the following modifications

Rated voltages	Primary: 100 ... 240V 50/60Hz 110V 0,6A / 220V 0,3A (mains fuse 2A slow blow) Secondary: 12V DC ⎓ / 42W (with forced ventilation) turn-on duration 100%
Temperature controlled ventilator	Ventilator powers up at 50°C Internal temperature
Inserted SpaceCom	
Power consumption	At 12V 2,5 to 4W (depending on used accessories) without battery charge (ca. 3W battery charge)

Electrical isolation	External interfaces have an electrical isolation of 4kV to the SpaceStation
Spark protection	acc. to IEC EN 60601-1-2:1993 and IEC EN 60601-2-24:1998
EMC	acc. to IEC EN 60601-1-2:1993 and IEC EN 60601-2-24:1998
Internal interfaces	Connection for battery pack Connection to electronics and interface to the pumps Compact Flash Slot for WLAN-interface
External Interfaces	USB-Master e.g. for memory sticks USB-Slave for connection of a PC Ethernet for integration of network PS2 Interface for barcode reader Serial interface
Optional battery, for power supply of SpaceCom at power failure/transport	
Type of battery	NiMH battery pack
Operating time of battery	approx. 2 h
Charging time	approx. 6 h

11.3 B. Braun SpaceCover comfort

Pillar cover of the SpaceStation	Covers outlet of mains voltage of SpaceStation below Makes comfortable carrying of a SpaceStation possible For central alarm of a SpaceStation For power supply of a SpaceStation at power failure/transport
Inserted electronics	
Power consumption	At 12V approx. 1W without battery charge (approx. 3W battery charge)
Loud speaker	For central audible alarm for SpaceStation
LED luminous fields	For central optical display of status of SpaceStation
Display- and operating unit	Display Status of Battery of Space Station Display Status of Battery of SpaceCom Display Mode of Operation Battery-/Mains operation. Switch on/off of the SpaceStation in battery mode Display of failures Release battery maintenance

Internal Interfaces	Interface to battery Interface to display- and operating unit
External Interface	Interface to SpaceStation
Optional battery, for power supply of the SpaceStation at power failure/transport	
Type of battery pack	NiMH battery pack
Operating time of battery	approx. 2 h with SpaceCom approx. 10 h without SpaceCom
Charging time	approx. 6 h
Weight	0.9 kg
Dimensions W x H x D	261 x 82 x 160 mm

11.4 B. Braun SpaceCover standard

Pillar cover of the SpaceStation	Covers outlet of mains voltage of SpaceStation below Makes comfortable carrying of a SpaceStation possible
Weight	0.6 kg
Dimensions W x H x D	261 x 82 x 160 mm

B. Braun SpaceStation 871 3140
B. Braun Perfusor® Space 871 3030
B. Braun Infusomat® Space 871 3050
B. Braun SpaceControl* 871 3090
B. Braun SpaceCom 871 3160
B. Braun SpaceCover standard 871 3147
B. Braun SpaceCover comfort 871 3145
B. Braun SpaceStation with SpaceCom integrated 871 3142

Recommended accessories for B. Braun SpaceStation:
fm mobil 872 1106
Battery-Pack SP (NiMH) 871 3180
PCA Button SP 871 3190
Extension lead SP 60 cm 871 3210
Extension lead SP 120 cm 871 3215
Extention lead SP 10 m 871 3315
Extention lead SP 15 m 871 3415
Connection Lead SP 12 V 871 3231
Connection Lead for Staff Call SP 871 3232

Recommended accessories for B. Braun SpaceCom:
Battery-Pack SP (NiMH) 871 3180
RS232 cross over cable SP 871 3237
RS232 connector converter SP 871 3238
WLAN card for SpaceCom 871 3184

*Availability only on request

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Material-No. 38917302 • Drawing No. M690700200F04 d
0208 • Printed on pulp bleached 100 % chlorine-free

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